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Application Number 09/820198  
 Filing Date March 28, 2001  
 First Named Inventor Bickenbach, Jackie  
 Group Art Unit 1651  
 Examiner Name Lankford, Jr., Leon

Attorney Docket No: 875.029US1

**US PATENT DOCUMENTS**

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
W	US-5,686,307	11/11/1997	Wille, Jr., J. J.			07/11/1995

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T <sup>2</sup>
W	WO-99/47644	09/23/1999	Kaur, P., et al.			

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
W		BICKENBACH, J. R., "A novel sorting method yields a pure population of viable stem cells which reforms a complete epidermis with long-term recombinant gene expression", Abstracts of the 60th Annual Meeting of The Society for Investigative Dermatology, Chicago, May 5-9, 1999, Published in the Journal of Investigative Dermatology, Vol. 112, No. 4 (April 1999), 2 pages	
		BICKENBACH, J. R., "Identification and Behavior of Label-retaining Cells in Oral Mucosa and Skin", J. Dent. Res., 122C, (August 1981), 1611-1620	
		BICKENBACH, J. R., et al., "Identification and Localization of Label-Retaining Cells in Hamster Epithelia", J. Invest. Dermatol., 82:6, (June 1984), 618-622	
		BICKENBACH, J. R., et al., "Label-Retaining Cells in Human Embryonic and Fetal Epidermis", J. Invest. Dermatol. 88, (January 1987), 42-46	
		BICKENBACH, J. R., et al., "Rate of loss of tritiated thymidine label in basal cells in mouse epithelial tissues", Cell Tissue Kinet, 19, (May 1986), 325-333	
		BICKENBACH, J. R., et al., "Selection and Extended Growth of Murine Epidermal Stem Cells in Culture", Experimental Cell Research 244, (1998), 184-195	
		BICKENBACH, J. R., et al., "Transduction of a Preselected Population of Human Epidermal Stem Cells: Consequences for Gene Therapy", Proceedings of the Association of American Physicians, III:3, XP-002182787, (May/June 1999), 184-189	
		BLAU, H., et al., "Gene therapy: Progress, problems, prospects", Nature Medicine, 3:6, (June 1997), 612-613	
		CHUNG, S. Y., "Expression of the Human Keratin Gene (K1) in Transgenic Mice is Tissue- and Development-Specific but Altered with Respect to Differentiation State", Molecular and Cellular Differentiation, 2(1), (1994), 61-81	
		COMPTON, C. C., et al., "Skin Regenerated from Cultured Epithelial Autographs on Full-Thickness Burn Wounds from 6 Days to 5 Years after Grafting", Laboratory Investigation, 60(5), (May 1989), 600-612	
		DELLAMBRA, E., et al., "Corrective Transduction of Human Epidermal Stem Cells in Laminin-5-Dependent Junctional Epidermolysis Bullosa", Human Gene Therapy, 9, (1998), 1359-1370	

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WBL		DENG, H., et al., "Sustainable cutaneous gene delivery", <u>Nature Biotech.</u> , 15(13), (December 1997), 1388-1391	
		FENJIVES, E. S., et al., "Loss of Expression of a Retrovirus-Transduced Gene in Human Keratinocytes", <u>J. Invest. Dermatol.</u> , 106(3), (March 1996), 576-578	
		FIBISON, W. J., "Gene Therapy", <u>Nursing Clinics of North America</u> , 35(3), (September 2000), 757-772	
		FLOWERS, M. E., et al., "Long-term transplantation of canine keratinocytes made resistant to G418 through retrovirus-mediated gene transfer", <u>Proc. Natl. Ada. Sci. USA</u> , 87(6), (March 1990), 2349-2353	
		FUCHS, E., "Epidermal Differentiation: The Bare Essentials", <u>J. Cell Biol.</u> , 111(6), (December 1990), 2807-2814	
		GARLICK, J. A., et al., "Keratinocyte Gene Transfer and Gene Therapy", <u>Crit Rev Oral Biol Med</u> , 7(3), (1996), 204-221	
		GARLICK, J. A., et al., "Retrovirus-Mediated Transduction of Cultured Epidermal Keratinocytes", <u>J. Invest. Dermatol.</u> , 97(5), (November 1991), 824-829	
		GHAZIZADEH, S., et al., "In vivo transduction of mouse epidermis with recombinant retroviral vectors: implications for cutaneous gene therapy", <u>Gene Therapy</u> , 6(7), (July 1999), 1267-1275	
		GOODELL, M. A., et al., "Isolation and Functional Properties of Murine Hematopoietic Stem Cells that are Replicating in Vivo", <u>J. Exp. Med.</u> , 183(4), (April 1996), 1797-1806	
		GREENHALGH, D., et al., "Epidermis: An Attractive Target Tissue for Gene Therapy", <u>J. Invest. Dermatol.</u> , 103(5), (November 1994), 63S-69S	
		JACKSON, K. A., et al., "Hematopoietic potential of stem cells isolated from murine skeletal muscle", <u>Proc. Natl. Acad. Sci.</u> , 96(25), (December 1999), 14482-14486	
		KHAVARI, P. A., "Therapeutic gene delivery to the skin", <u>Molecular Medicine Today</u> , 3, (1997), 533-538	
		KORGE, B. P., et al., "The molecular basis for inherited bullous diseases", <u>J. Biol. Med.</u> , 74(2), (February 1996), 59-70	
		MACKENZIE, I., et al., "Influence of Connective Tissues on the In Vitro Growth and Differentiation of Murine Epidermis", <u>Epith. Cell Biol.</u> , 2(3), (1993), 107-119	
		MACKENZIE, I., "Retroviral Transduction of Murine Epidermal Stem Cells Demonstrates Clonal Units of Epidermal Structure", <u>J. Invest. Dermatol.</u> , 109(3), (September 1997), 377-383	
		MORGAN, J. R., et al., "Expression of an Exogenous Growth Hormone Gene by Transplantable Human Epidermal Cells", <u>Science</u> , 237, (September 1987), 1476-1479	
		MORRIS, R. J., et al., "Highly Persistent Label-Retaining Cells in the Hair Follicles of Mice and Their Fate Following Induction of Anagen", <u>J. Invest. Dermatol.</u> , 112(4), (April 1999), 470-475	

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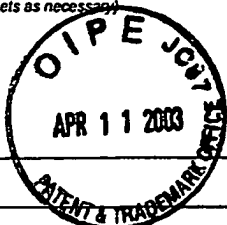
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WJL	✓	MOUNTAIN, A. , "Gene therapy: the first decade", <u>Trends in Biotechnology</u> , 18(3), (March 2000),119-128	
	✓	OTTO, W. R., et al., "Survival of Allogeneic Cells in Cultured Organotypic Skin Grafts", <u>Plast. Reconstr. Surg.</u> , 96(1), (July 1995),166-176	
	✓	REDDI, A. H., "Morphogenesis and tissue engineering of bone and cartilage: inductive signals, stem cells, and biomimetic biomaterials", <u>Tissue Engineering</u> , 6(4), (2000),351-359	
	✓	RHEINWALD, J. G., et al., "Serial cultivation of strains of human epidermal keratinocytes: the formation of keratinizing colonies of single cells", <u>Cell</u> , 6(3), (November 1975),331-344	
	✓	ROTHNAGEL, J. A., et al., "Analysis, diagnosis, and molecular genetics of keratin disorders", <u>Current Opinion in Dermatology</u> , (1995),211-218	
	✓	SANES, J. R., "Analysing cell lineage with a recombinant retrovirus", <u>Trends in Neurosciences</u> , 12(1), (1989),21-28	
	✓	STENN, K. S., et al., "Dispase, a neutral protease from Bacillus Polymyxa, is a powerful fibronectinase and Type IV collagenase", <u>J. Invest. Dermat.</u> ,93(2), (August 1989),287-290	
	✓	VOGEL, J. C., "Keratinocyte Gene Therapy", <u>Arch. Dermat.</u> , 129, (November 1993),1478-1483	
	✓	VOGT, P. M., et al., "Genetically modified keratinocytes transplanted to wounds reconstitute the epidermis", <u>Proc. Natl. Acad. Sci.</u> , 91(20), (September 1994),9307-9311	
WJL	✓	WALTHER, W. , et al., "Therapeutic genes for cancer gene therapy", <u>Molecular Biology</u> , 13(1), (November 1999),21-28	
	✓	WANG, F. , et al., "Gene therapy and metabolic engineering", <u>Metabolic Engineering</u> , 2, (2000),126-139	

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Substitute Disclosure Statement Form (PTO-1449)

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